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10/608,305	06/27/2003	Liang C. Dong	ARC 3251 R1	8986
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LANDAU, SHARMILA GOLLAMUDI				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/608,305

Applicant(s)

DONG ET AL.

Examiner

Sharmila Gollamudi Landau

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-10, 13 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-10, 13, 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Receipt of Request for Continued Examination and Amendments/Remarks filed 12/18/07 is acknowledged. Claims 1, 4-10, 13, 17-24 are pending in this application. Claims 1, 4-10, 13, and 17-24 are directed to the elected invention. Claims 2-3, 11-12, 14-16, 25-36 stand cancelled.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments of 12/18/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-10, 17-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claim 1 and 13, respectively, recite a reservoir formed of a material that is impermeable wherein the expandable osmotic composition is positioned within the reservoir. Dependent claims are directed to a multilayer reservoir. The multilayered reservoir does not support the embodiment of partially containing the osmotic composition within the reservoir. Figure 1 of the instant application is directed to a single layer reservoir and supports that the recitation the expandable osmotic composition is positioned within the reservoir. Thus, only

independent claims 1 and claim 13 respectively are supported. However, Figure 2, which is directed to a multilayered reservoir, does support the recitation that the expandable osmotic composition (18) is positioned within the reservoir since the reservoir is defined as being formed of an impermeable material (16). Thus, the dependent claims directed to the multilayered reservoir partially containing the osmotic composition, are not supported.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-10, and 17-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 and 13, respectively, recite "a reservoir formed of a material that is impermeable". However, dependent claims are directed to the reservoir comprising a water permeable material and a water impermeable subcoat. The claims are vague and indefinite since the independent claims are directed to a reservoir that is formed of an impermeable material. The use of the language "formed of" appears to limit the reservoir solely to an impermeable material. It is noted that "material" can be interpreted as a "component" or "layer or coat". If the hydrophilic material is interpreted as a "layer", then the reservoir cannot contain another layer as claimed in the dependent claims since the independent claim is limiting the reservoir to an impermeable material as discussed above. If the hydrophilic component is interpreted as a "component", this would render the claim indefinite for the following reasons: it is noted that a hydrophilic material added to an impermeable material renders a semi-permeable that is permeable to water.

Therefore, it is unclear if applicant intends to claim a reservoir that comprise an impermeable component and a hydrophilic component, i.e. forming a semi-permeable material or if applicant intends to claim multiple layers to form the reservoir, as seen in instant Figure 2. It appears, from the recitation, “a water impermeable subcoat provided over the hydrophilic material” in the dependent claims, that applicant intends to claim the latter. If applicant intends to claim the latter, then it is suggested that applicant amend the independent claims to “a reservoir *comprising* an impermeable coat”. If the former is intended to be claimed, i.e. a reservoir formed of an impermeable component and a hydrophilic component, i.e. forming a semipermeable membrane, then the examiner suggests that applicant clarify that the first layer comprises a hydrophilic material and a impermeable material, which is coated with a water impermeable layer over the first layer to form a multi-layered reservoir. Note applicant may not have support in the specification as originally filed for this. Summarily, since the independent claims are limited to an impermeable material, then the reservoir cannot contain a hydrophilic material as recited in the dependent claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

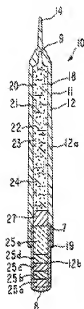
A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 10, 13, 17, and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong (5,312,390) is withdrawn in light of applicant's amendments filed 12/18/07.

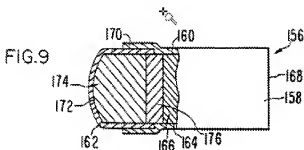
Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 373867 to Magruder et al.

FIG. 9



Magruder et al discloses a delivery system comprising a housing member (12) that is comprises of two sections 12(a) and 12(b). Section 12(a), the reservoir, is impermeable to external fluids and houses the liquid drug (20) and houses a first portion of an expandable osmotic composition, 25 (a-c)), which extends outwardly form the distal end of the reservoir. Section 12(a) is a membrane that is permeable to fluids. The reservoir contains an exit (14), a break off tab. Magruder discloses the expandable driving means comprising an osmotic effective compounds including osomopolymers and osmotic solutes. see column 22. Example 1 discloses a liquid drug formulation.

Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al (5,391,381).



Wong et al disclose an oral dosage form for delivering an active formulation as a liquid, solid, or semi-solid. See column 4, lines 15-20. Wong et al disclose the “drug unit” or “active agent unit” include units that are capable of maintaining their physical configuration and chemical integrity while housed within the dispenser, which includes, tablets or capsules. See column 4, lines 23-37. The examples utilize gelatin capsules. The dispenser comprises a wall section 160, the reservoir, which is impermeable to the exchange of fluid, drug and other ingredients contained in the delivery system. The reservoir contains the drug formulation, 166. Wall section 162 is a semipermeable wall composition that is permeable to the passage of fluid for making fluid available to an expandable osmotic driving means 174. Further, the gelatin capsule and housing “dispenser” wall 160 form a multilayer reservoir. 168 is the exit port.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-5, 10, 17-18, 23-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (5,391,381).

Wong et al disclose an oral dosage form for delivering an active formulation as a liquid, solid, or semi-solid. See column 4, lines 15-20. Wong et al disclose the “drug unit” or “active agent unit” include units that are capable of maintaining their physical configuration and chemical integrity while housed within the dispenser such as tablets or capsules. See column 4, lines 23-37. Two piece gelatin capsules are taught. Wong teaches FIGS. 1, 2, 3 and 8 illustrate various embodiments of the dispensing component suitable for use in the dispenser and these configurations can be combined with various embodiments of the driving component, representative embodiments of which are illustrated in FIGS. 4-7, and of the housing structure itself, shown in FIGS. 1, 4, 6, 9-13 and 15.

Wong et al do not exemplify the use of the gelatin capsule with the embodiment taught in Figure 9.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a gelatin capsule to contain the drug formulation within wall 160. One would have been motivated to do so with a reasonable expectation of success since Wong et

Art Unit: 1611

al disclose that the active formulation may be contained in a capsule to maintain its physical configuration and chemical integrity. Thus, when formulating the oral dosage form, it would have been obvious to formulate the drug in a capsule body to confine it and protect it prior to coating the impermeable substance, if the drug is a sensitive.

Regarding claim 24, it would have been further obvious to have the overlapping walls of 162 and 160 configured to overlap in a manner in which 162 overlaps 160, absent the unexpectedness of the configuration, since both configurations provide the overlapping region of 160 and 162.

Claims 6-7, 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (5,391,381) in further view of Digenis (5,672,359).

The teachings of Wong have been set forth above. As discussed above, Wong teaches when forming the device, two portions of a hard gelatin capsule may be coated, one with an impermeable material and the other with a semipermeable material.

Wong does not teach the instant hydrophilic polymer.

Digenis while teaches a hard capsule for controlled release, teaches the hard capsule made by made from hydrophilic materials such as gelatin or hydroxypropylmethylcellulose. See column 1, lines 10-15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wong and Dong and utilize HPMC as the material form the capsule portion. One would have been motivated to do so with a reasonable expectation of similar results since Digenis teaches hard capsules may be made from hydrophilic materials such as instant HPMC or gelatin. Thus, a skilled artisan would have been motivated to substitute the

Art Unit: 1611

prior art's gelatin material with the instant hydrophilic material with a reasonable expectation of success since Digenis establishes the functional equivalency of the prior art's hydrophilic material and the instant hydrophilic material, i.e. both are hydrophilic materials that are used to form hard capsules.

Claims 8-9 and 21-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (5,391,381) in further view of Dong (WO 0035419).

The teachings of Wong have been set forth above. Wong teaches impermeable materials for the dispenser's wall 160 including polymethylacrylates, polyethylene terphthalate, rubber, polyvinyl chloride, polystyrene, and any other material that is biologically suitable for fabrication of the impermeable component. See column 5, lines 1-20.

Wong does not teach the instant impermeable polymethacrylate latex material.

Dong teaches a controlled release system comprising liquid drugs. See abstract. Dong while teaching a barrier layer that is impermeable to fluids, teaches suitable materials include latex materials such as latex of acrylate esters EUDRAGIT, polymethylacrylates, polyethylene terphthalate, rubber, polyvinyl chloride, polystyrene. See page 19, lines 22-25 and page 20, lines 14-26.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wong and Dong and utilize the instantly claimed impermeable material for wall (160). One would have been motivated to do so with a reasonable expectation of similar results since Wong teaches the use of any impermeable material known in the art including polymethylacrylates, polyethylene terphthalate, rubber, polyvinyl chloride, and polystyrene and Dong teaches latex of acrylate esters, along with polymethylacrylates,

Art Unit: 1611

polyethylene terephthalate, rubber, polyvinyl chloride, polystyrene are known materials that are impermeable to fluids. Thus, Dong teaches the same impermeable materials taught by Wong and thus establishes the functional equivalency between the instant latex material and the prior art's impermeable material.

Conclusion

Claims 1, 4-10, 13, 17-24 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharmila Gollamudi Landau/
Primary Examiner, Art Unit 1611

